



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/039,845

10/23/2001

Shlomo Ben-Haim

298858-00056

1690

83380 7590 06/01/2009  
Eckert Seamans Cherin & Mellott, LLC  
U.S. Steel Tower  
600 Grant Street, 44th Floor  
Pittsburgh, PA 15219

EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3766

NOTIFICATION DATE

DELIVERY MODE

06/01/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmail@eckertseamans.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/039,845	<b>Applicant(s)</b> BEN-HAIM ET AL.	
	<b>Examiner</b> FRANCES P. OROPEZA	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/12/09 (Amendment).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5 and 10-27 is/are pending in the application.
- 4a) Of the above claim(s) 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5 and 10-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/5/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Requested for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/09 has been entered.

### ***Response***

2. The Applicant amended independent claim 5 and added claims 15-27 in the response filed 3/12/09, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

### ***Claim Rejections - 35 USC § 101***

3. Newly submitted claims 26 and 27 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention currently being prosecuted limits the invention to a first and a second stimulus, the first and second effects being different from each other. Newly submitted claims do not have this limitation, hence this creates a distinct invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 26 and 27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22 appears to be redundant of claim 5, and should be cancelled.

***Claim Rejections - 35 USC § 102***

6. Claims 5, 10-21 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Zipes (U.S. Patent No. 4,384,585).

Zipes discloses a heart control apparatus generating non-excitatory stimulus in the area of the heart involved in the genesis and maintenance of tachyarrhythmias, where the first stimulation has a first effect on the first area of the heart and the second stimulation has a second effect on the second area of the heart, such that the relationship between the areas stimulated modifies the relationship between the contractions in these two areas of the heart. The areas of the heart treated can be the atria or ventricles. When the ventricles are determined to originate and maintain the tachyarrhythmia, the ventricles are simultaneously controlled and stimulated for a few beats every certain period of time, to increase the flow from one ventricle and decrease the flow from the other ventricle (abstract; column 1, lines 31-34; column 1, line 55 – column 2, line 3; column 3, lines 12-18, 38-43; column 4, lines 6-11; column 4, line 37 – column 5, line 4).

Note the concept of non-excitatory stimulation amounts to an intended use limitation of which Zipes inherently performs or is capable of performing.

Claim 5 is an apparatus claim, and an apparatus claim is limited by structure. The newly added limitation "wherein said first effect is not prevention or amelioration of arrhythmia" does not provide for any alteration or further detail related to the structure of the apparatus, hence the newly added limitation is viewed as having a limited impact on the scope of the claim and claim 5 is rejected.

As to claims 14 and 25, the stimulation is periodically delivered in response to a detected intrinsic ventricular depolarization, hence for a patient with periodic intrinsic activity, the device will control the heart for a few beats, every certain period of time using non-excitatory stimuli.

As to claim 15, 19, 20 and 24, the stimulation is accepted to modify the contractility hence it is accepted to be excitatory .

As to claims 16, 17 and 21, the system, including circuitry, is accepted to impact non-arrhythmic tissue during period when no arrhythmia activity is present.

As to claims 18 and 23, the treatment impacts arrhythmias, cardiac rhythms accepted to have low cardiac output, hence the stimuli are accepted to increase cardiac output.

7. Claims 5, 10, 11, 13-21 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Prystowsky et al. (U.S. Patent No. 4,554,922).

Prystowsky et al. disclose a heart control apparatus generating non-excitatory stimulus in heart tissue during the refractory period of the cardiac cycle, where the first stimulation has a first effect on the first area of the heart and the second stimulation has a second effect on the second

Art Unit: 3766

area of the heart, such that the relationship between the contractions in these two areas of the heart is modified. For example, when the right ventricular contraction is modified, this changed results in a modification of the relationship to the left ventricle. Single or multiple areas of the heart can be simultaneously stimulated for a few beats every certain period of time (abstract; column 1, lines 28-36; column 54 – column 2, lines 11).

Note the concept of non-excitatory stimulation amounts to an intended use limitation of which Prystowsky et al. inherently performs or is capable of performing.

Claim 5 is an apparatus claim, and an apparatus claim is limited by structure. The newly added limitation "wherein said first effect is not prevention or amelioration of arrhythmia" does not provide for any alteration or further detail related to the structure of the apparatus, hence the newly added limitation is viewed as having a limited impact on the scope of the claim and claim 5 is rejected.

As to claims 14 and 25, the stimulation is selectively delivered to inhibit cardiac arrhythmias, hence for a patient with periodic arrhythmias, the device will control the heart for a few beats, every certain period of time, every certain period of time using excitatory stimuli.

As to claim 15, 19, 20 and 24, the stimulation is accepted to be excitatory and modify the contractility, either increasing or decreasing the contractility.

As to claims 16, 17 and 21, the system, including circuitry, is accepted to impact non-arrhythmic tissue during period when no arrhythmia activity is present.

As to claims 18 and 23, the treatment impacts arrhythmias, cardiac rhythms accepted to have low cardiac output, hence the stimuli are accepted to increase cardiac output and be excitatory in nature.

***Claim Rejections - 35 USC § 103***

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prystowsky et al. (U.S. Patent No. 4,554,922) in view of Zipes (U.S. Patent No. 4,384,585).

As discussed in paragraph 7 of this action, Prystowsky et al. disclose the claimed invention except for the heart control apparatus controlling both ventricles.

Zipes teaches synchronized cardioverting using a lead configuration that delivers a electrical stimulation to both ventricles of the heart for the purpose of treating the point of origin and maintenance of tachycardia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a lead configuration that delivers a charge to both ventricles of the heart in the Prystowsky et al. in order to use a proven treatment that includes both ventricular areas in the heart, so a more comprehensive treatment can be applied to the cardiac tissue of the patient, so the tachycardia can be successful treated, and the development of fibrillation can be avoided (column 1, lines 31-34, 61-66; column 3, lines 12-18, 24-31; column 4, lines 6-11).

***Statutory Basis***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 3766

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM-5 PM EST; Tuesday, Thursday 9AM-3PM and 9PM-11PM EST. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Frances P. Oropeza/  
Patent Examiner, Art Unit 3766  
May 26, 2009

/Carl H. Layno/  
Supervisory Patent Examiner, Art Unit 3766



Application/Control Number: 10/039,845  
Art Unit: 3766

Page 8